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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,966	11/03/2003	John Henry Kenten	100390-03578	5067

35745 7590 11/01/2006

KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,966

Applicant(s)

KENTEN ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-127 and 133-181 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 124-127 and 133-181 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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After reading applicants' election, amendment of the claims and remarks, the following second restriction requirement is deemed needed:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 124-125, 133, drawn to a method of synthesizing a bispecific antibody comprising VH antibody 1-S-VL antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 530, subclass 387.3.
- II. Claims 124-125, 133, drawn to a method of synthesizing a bispecific antibody comprising VH antibody 1-S-VL antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 530, subclass 387.3.
- III. Claims 124-125, 133, drawn to a method of synthesizing a bispecific antibody comprising VL antibody 1-S-VH antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 530, subclass 387.3.
- IV. Claims 124-125, drawn to a method of synthesizing a bispecific antibody comprising VL antibody 1-S-VH antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 530, subclass 387.3.
- V. Claims 126, 134-135,, drawn to a method of making a bispecific antibody comprising expressing the sequence VL antibody 1-S-VH antibody 2 and the sequence VH antibody 1-S-VL antibody 2 and combining the two products, classified in class 530, subclass 387.3.
- VI. Claims 127, 136-137, drawn to a method of making a bispecific antibody comprising expressing the sequence VL antibody 2-S-VH antibody 1 and the sequence VH antibody 2-S-VL antibody 1 and combining the two products, classified in class 435, subclass 188.5 and class 530, subclass 387.3.

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- VII. Claims 138-140, drawn to a method of making a bispecific antibody comprising expressing a single chain protein comprising the VH and VL regions of a first antibody and the VH and VL regions of a second antibody, classified in class 530, subclass 387.3.
- VIII. Claims 141-143, drawn to a method of making a bispecific antibody comprising expressing a single chain protein comprising the VH and VL regions of a first antibody and the VH and VL regions of a second antibody, expressing a single chain protein comprising the VL region of the first antibody and the VH regions of the second antibody and combining the two, classified in class 435, subclass 188.5 and class 530, subclass 387.3.
- IX. Claims 144-145, drawn to a method of making a bispecific antibody comprising expressing two single chain polypeptides, each comprising a VH and VL region, and combining the two single chain polypeptides, classified in class 530, subclass 387.3.
- X. Claims 176-177, drawn to an antibody comprising one antibody VH region from a first antibody and one antibody VL region from a second antibody, having the sequence VL antibody 2-S-VH antibody 1, classified in class 530, subclass 387.3.
- XI. Claims 176-177, drawn to an antibody comprising one antibody VH region from a first antibody and one antibody VL region from a second antibody, having the sequence VH antibody 1-S-VL antibody 2, classified in class 530, subclass 387.3.
- XII. Claims 146-159, 176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second VL region from the first antibody and a second VH region from the second antibo-

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dy, having the sequence VH antibody 1-S-VL antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 435, subclass 188.5 and class 530, subclass 387.3.

- XIII. Claims 146-159, 176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second VL region from the first antibody and a second VH region from the second antibody, having the sequence VH antibody 1-S-VL antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 435, subclass 188.5 and class 530, subclass 387.3.
- IX. Claims 146-159, 176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second VL region from the first antibody and a second VH region from the second antibody, having the sequence VL antibody 1-S-VH antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 435, subclass 188.5 and class 530, subclass 387.3.
- X. Claims 146-159, 176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second VL region from the first antibody and a second VH region from the second antibody, having the sequence VL antibody 1-S-VH antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 435, subclass 188.5 and class 530, subclass 387.3.
- XI. Claims 160-173, 176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second VL region from

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the first antibody and a second VH region from the second antibody, the sequence of the first polypeptide comprising VL antibody 1-S-VH antibody 2 and the second polypeptide comprising VH antibody 1-S-VL antibody 2, a vector containing the nucleic acid encoding the antibody, a host cell that produces the antibody, a bacteriophage containing the nucleic acid, classified in class 435, subclass 188.5, 320.1, 235.1, 252.3 and class 530, subclass 387.3.

- X. Claims 174-176, drawn to an antibody comprising one antibody VH region from a first antibody, one antibody VL region from a second antibody and further comprising a second single chain polypeptide comprising a VH region and a VL region, classified in class 530, subclass 387.3.
- XI. Claims 178-179, drawn to a gene encoding a polypeptide chain comprising the VH and VL from both a first antibody and a second antibody, the sequence being VH antibody 1-S-VL antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 536, subclass 23.4.
- XII. Claims 178-179, drawn to a gene encoding a polypeptide chain comprising the VH and VL from both a first antibody and a second antibody, the sequence being VH antibody 1-S-VL antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 536, subclass 23.4.
- XIII. Claims 178-179, drawn to a gene encoding a polypeptide chain comprising the VH and VL from both a first antibody and a second antibody, the sequence being VL antibody 1-S-VH antibody 1-S-VL antibody 2-S-VH antibody 2, classified in class 536, subclass 23.4.
- XIV. Claims 178-179, drawn to a gene encoding a polypeptide chain comprising the VH and VL from both a first antibody and a second an-

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tibody, the sequence being VL antibody 1-S-VH antibody 1-S-VH antibody 2-S-VL antibody 2, classified in class 536, subclass 23.4.

XV. Claims 180-181, drawn to a gene encoding a polypeptide chain comprising on antibody VH region for a first antibody and a VL region from a second antibody, having the sequence VL antibody 2-S-VH antibody 1, classified in class 536, subclass 23.4.

XVI. Claims 180-181, drawn to a gene encoding a polypeptide chain comprising on antibody VH region for a first antibody and a VL region from a second antibody, having the sequence VH antibody 1-S-VL antibody 2, classified in class 536, subclass 23.4.

It is noted that claim 161 is confusing and indefinite in that "first polypeptide" in line 2 has no antecedent basis. Claim 174 is likewise confusing and indefinite in that "a second single chain polypeptide" in line 2 has no antecedent basis.

The inventions are independent or distinct, each from the other because:

Each of the groups are drawn to methods or bispecific antibodies having different combinations of antibody fragments. Therefore they are structurally different and patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 27, 2006